

510 (k) Summary

June 25, 2013

Submitter: Peregrine Surgical
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JUN 26 2013**Official Correspondent:** Ryan O'Leary**Trade Name:** 23ga Curved Illuminating Laser Probe**Common Name:** Ophthalmic Laser Probe**Registration Number:** 2529392**Classification:**

	Primary	2nd	3rd
Regulation Number:	21 CFR 886.4690	21 CFR 876.1500	21 CFR 886.4390
Regulation Name:	Ophthalmic Photocoagulator	Endoscope and Accessories	Ophthalmic Laser
Class:	II	II	II
Product Code:	HQB	MPA	HQF

Device Description: The 23ga Curved Illuminating Laser Probe was designed with intentions of selling it to Bausch & Lomb for distribution. The 23ga Curved Illuminating Laser Probe is an ophthalmic light and laser delivery device. It consists of glass fiber with PVC jacket, an SMA connector, an acetal handpiece and a needle set consisting of 304 stainless steel and nitinol. There is also an acrylic fiber with PVC jacket and an acetal connector. Both connectors plug into existing laser and light sources.

The device is designed to be an accessory for an Iridex medical laser (cleared under K071687) in the Vis-NIR transmission range of 532 nm to 810 nm with a maximum power output of 2.5 Watts and that is appropriate for photocoagulation. The device can be used with other lasers but they must be FDA approved and also meet the above specifications. The light portion of the device was designed for use with the Bausch & Lomb Stellaris PC light source which is a component of the Bausch & Lomb Stellaris PC Vision Enhancement System (cleared under K101325). The Stellaris PC uses a 75 Watt Xenon arc lamp that emits light with an output of 30 lumens within the wavelength range of 441nm to 665nm (photocoagulation is not applicable to the illumination aspect of the probe).

The outer dimension of the glass fiber to be used in the proposed device is 195 microns or about .008 inches (with a core of 150 microns), which is about 80% of the total diameter of the glass fiber in the predicate device. The acrylic fiber that will be used has an outer dimension of 240 microns or .0095 inches, which is 25% of the total diameter of the acrylic fiber used in the predicate device. The decrease

in size of both fibers has created an acceptable device. The change in performance is discussed in the Substantial Equivalence section.

Statement of Indications for Use: For photocoagulation and illumination during ophthalmic surgery. This device delivers illumination as well as laser energy to target tissue, causing coagulation. Spot size can be varied by altering the distance between the tissue and the probe tip.

The *Indications for Use* for the proposed device as described in the labeling, are identical to those of the predicate device.

Substantial Equivalence Comparison: The 23ga Curved Illuminating Laser Probe is equivalent to Peregrine's Illuminated Laser Probe (PD600.10 – 510(k) #K031023) except for the curved nitinol needle, the smaller glass laser fiber, the smaller acrylic illumination fiber, the jacket color and the illumination connector. Peregrine will be using smaller fibers to accommodate the smaller needle size for small gauge surgery. The new smaller fibers are comprised of the same materials as the larger fibers and are manufactured by the same company using the same processes.

Product PD600.10 K031023 Peregrine Illuminated Laser Probe	23ga Curved Illuminating Laser Probe Manufactured by Peregrine
Illumination and laser transmission for Photocoagulation	Illumination and laser transmission for Photocoagulation
Ni/Cu Stainless Alloy Connector	Ni/Cu Stainless Alloy Connector
Delrin Handpiece	Delrin Handpiece
Optical Fiber	Optical Fiber
Glass - Silica Core .008" (200 microns)	Glass - Silica Core .006" (150 microns)
Max Threshold of Laser Fiber: 3000 mW	Max Threshold of Laser Fiber: 3000 mW
Transmission Range of Laser Fiber: 180nm to 1,150nm	Transmission Range of Laser Fiber: 180nm to 1,150nm
Laser Power Efficiency ≈ 95.5%	Laser Power Efficiency ≈ 95.0%
Laser Spot Size ≈ 2.0 inches	Laser Spot Size ≈ 1.90 inches
PVC Jacket (Black)	PVC Jacket (Orange)
PVC Jacket - ID .040"/OD .070"	PVC Jacket - ID .040"/OD .070"
Length: 101 Inches	Length: 101 Inches
Weight: 31.6 grams	Weight: 26.0 grams
304 Stainless Needle	304 Stainless and Nitinol Needle
20 Gauge	23 Gauge
Acrylic Illumination Fiber - .01" OD	Acrylic Illumination Fiber - .0095" OD
Aluminum Illumination Connector	Delrin Illumination Connector

The three aspects of performance potentially affected by the changes are light output, laser power output and laser field clarity. Peregrine performed 3 performance tests to determine substantial equivalence to Peregrine's Illuminated Laser Probe in safety and effectiveness. The light output of the proposed device is less than the predicate device but this is a recognized and unavoidable by product of using smaller

gauge surgical instruments. Surgeons understand that light outputs are compromised due to the use of smaller needle/tube gauges and smaller fibers used in the production of smaller gauge instruments. Therefore, the light output of the proposed device is acceptable and, therefore, substantially equivalent. Testing results showed that both laser power output and laser field clarity were nearly identical between the predicate and proposed devices. Therefore, the devices were substantially equivalent with respect to laser power output and laser field clarity.

Nitinol, which is used in the needle set of the 23ga Curved Illuminating Laser Probe, is used in several other FDA market-approved ophthalmic devices. Alcon's 25+ Flex-Tip Laser Probe (K062624) is one example. Iridex also manufactures an ophthalmic surgical device containing nitinol. This shows that nitinol is an approved material to be used in ophthalmic surgical devices. Biocompatibility testing was performed on the entire device. The results of the testing shows 100% biocompatibility and, therefore, demonstrates the biocompatibility of the nitinol as well as the stainless steel, acrylic and glass fiber, PVC and Delrin®.

The reason for using nitinol in the 23ga Curved Illuminating Laser Probe is to allow for slight flexibility to help facilitate insertion through 23ga cannula systems. Cannula test results show that the nitinol needle set of the proposed device displayed no resistance when passing through the cannula system. "Bend testing" was performed on both the existing and proposed design in order to evaluate safety and performance. The proposed needle set proved to be safe and effective and therefore, substantially equivalent to the predicate device.

The PVC jacket color has been changed simply to differentiate this laser probe from other gauges and styles. The orange jacket is made from the same materials, using the same processes as all other PVC jacket used in other Peregrine laser probes. The only difference is the dye used, which is FDA approved.

The light connector for the 23ga Curved Illuminating Laser Probe is designed to fit into the light source of the B&L Stellaris PC Vision Enhancement System. Peregrine has been using the Stellaris connector in the manufacture of many products since the inception of the Stellaris in 2007. The change from the aluminum connector to the Delrin® connector accounts for all of the weight difference between the predicate and modified devices.

The Transmission Efficiency of the proposed design was measured and compared to the predicate design using 3 different types of lasers. The results show that both designs are nearly identical in laser transmission efficiency.

The approved predicate Peregrine device and the proposed Peregrine device are both used in the same way. The devices are plugged into a laser/light source with the appropriate connectors and the laser and light are delivered to the surgical site through the applicable fibers.

This information demonstrates that the 23ga Curved Illuminating Laser Probe is substantially equivalent to the predicate device.

Optical Radiation Safety

The Peregrine illuminating laser probe only "transmits" the laser/light energy. It does not control its intensity or power output. The light portion of the device was designed for use solely with the Bausch &

Lomb Stellaris PC light source which is a component of the Bausch & Lomb Stellaris PC Vision Enhancement System (cleared under K101325). The Stellaris PC uses a 75 Watt Xenon arc lamp that emits light with an output of 30 lumens within the wavelength range of 441nm to 665nm. Performance testing indicates that the light “transmission” is less from a 23ga Curved Illuminating Laser Probe (BL5293LC) as compared to the “transmission” from the predicate device (PD600.10). Therefore, the substantial equivalence in optical radiation safety is established.

Biocompatibility

The nitinol to be used in the 23ga Curved Illuminating Laser Probe has been tested for biocompatibility and is approved for medical use (including implantation). In addition, biocompatibility testing was performed on the 25ga Curved Illuminating Laser Probe with nitinol tip as detailed in the Peregrine Surgical Memo dated August 3rd, 2012 by Jayne Guthrie (included with this submission). The nitinol used to manufacture Peregrine’s 25ga Curved Illuminating Laser Probe is the same nitinol used to manufacture the 23ga Curved Illuminating Laser Probe. Test results demonstrate that all materials used to manufacture this final device, including nitinol, are biocompatible and safe for the use in which it is intended.

Sterility

The Device will be sterilized using ETO Sterilization. The SAL is 10 to -6.

The method used to validate the sterilization cycle is AAMI Overkill Method according to ISO 11135-1.

Packaging material will be Tyvek to Poly pouches.

All materials used in manufacturing the device are biocompatible and data is kept on file.

The Probes will have a shelf life of 4 years from sterilization.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

June 26, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - W066-G609
Silver Spring, MD 20993-0002

Peregrine Surgical Ltd.
c/o Mr. Ryan O'Leary
51 Britain Dr.
New Britain, PA 18901

Re: K122997

Trade Name: 23 ga Curved Illuminating Laser Probe
Regulation Number: 21 CFR 886.4690
Regulation Name: Ophthalmic Photocoagulator
Regulatory Class: Class II
Product Code: HQB, HQF, MPA
Dated: June 13, 2013
Received: June 14, 2013

Dear Mr. O'Leary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122997

Device Name: 23ga Curved Illuminating Laser Probe

Indications for Use:

For photocoagulation and illumination during ophthalmic surgery. This device delivers illumination as well as laser energy to target tissue, causing coagulation. Spot size can be varied by altering the distance between the tissue and the probe tip.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Dexiu Shi -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Dexiu Shi-S,
0.9.2342.1920030010019151300157347
Date: 2013.06.25 13:35:44 -04'00

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose
and Throat Devices

510(k) Number K122997